

MAR 29 2006

K052383



**Premarket Notification 510(k) Summary
as required by 21 CFR 807.92**

Date summary was prepared:

February 15, 2006

Manufacturer's Name:

Innocure, LLC
201 East Southern Avenue
Suite 201
Tempe, AZ 85282-5133

Contact Person:

Donald W. Collins, Ph.D.
Chairman and CTO
201 East Southern Avenue
Suite 201
Tempe, AZ 85282-5133

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Cell: 602-319-8620
Email: Donald.collins@innocure.com

Trade Name:

Innocure Intensity Modulating Radiation Therapy Compensators including:

Innocure IMRT Filter™
Innocure IMRT Radiation Blocking Filter™
Innocure Radiation Wound Protective Blocking Filter™

Common Name:

Compensating Filters

Classification Name:

Radiation Therapy Beam Shaping Block (21 CFR §892.5710, Product Code: IXI)

**Predicate Device:**

Southeastern Radiation Products, Inc., K040804, “.Decimal Tissue Compensator/Intensity Modulator”.

Device Descriptions:

An “Innocure IMRT Filter™ (Compensator)” consists of a precision milled solid block of Aluminum (6061T6), a solid block of Brass 360, or a precision milled reverse Styrofoam or Polyurethane Mold filled with Molten Cerrobend or Tungsten Metal Powder identified with linear accelerator orientation markings and patient radiation therapy plan and field identification. The Compensator device is placed in the linear accelerator beam path between the radiation source and the patient by mounting it to a block tray.

An “Innocure IMRT Radiation Blocking Filter™ (Compensator)” consists of a precision milled solid block of Aluminum (6061T6), a solid block of Brass 360, or a precision milled reverse Styrofoam or Polyurethane Mold filled with Molten Cerrobend or Tungsten Metal Powder identified with linear accelerator orientation markings and patient radiation therapy plan identification. The Blocking device is placed in the linear accelerator beam path between the radiation source and the patient by mounting it to a block tray.

An “Innocure Radiation Wound Protective Filter™ (Compensator)” consists of a precision milled solid block of Aluminum (6061T6), a solid block of Brass 360, or a precision milled reverse Styrofoam or Polyurethane Mold filled with Molten Cerrobend or Tungsten Metal Powder identified with linear accelerator orientation markings and patient radiation therapy plan identification. The device is placed in the linear accelerator beam path between the radiation source and the patient by mounting it to a block tray.

Intended Use:

Innocure Intensity Modulating Radiation Therapy Compensators are intended to be used for external beam radiation therapy to modulate the intensity and shape of a radiation beam to compensate for missing tissue, for tissue heterogeneities, or to protect underlying tissue by intensity modulation, i.e. Intensity Modulated Radiation Therapy (IMRT).

Technological Characteristics:

Innocure manufactures Intensity Modulated Radiation Therapy (IMRT) filters from a solid Aluminum (6061T6) block, solid Brass 360 block, and a reverse Styrofoam or Polystyrene Mold block to be filled with Molten Cerrobend or Tungsten Powdered Metal.



Conclusions:

The subject devices, “Innocure “Innocure IMRT Filter™ (Compensators)”, “Innocure IMRT Radiation Blocking Filters™ (Compensators)” and “Innocure Radiation Wound Protective Filters™ (Compensators)” for Radiation Therapy have the same intended use and similar characteristics as the predicate device and does not introduce new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 29 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Donald W. Collins, Ph.D.
Chairman and CTO
Innocure, LLC
201 East Southern Avenue
Suites 201 & 202
TEMPE AZ 85282-5133

Re: K052383
Trade/Device Name: Innocure Intensity Modulating
Radiation Therapy Compensators including:
Innocure IMRT Filter™, Innocure IMRT Radiation
Bolcking Filter™, Innocure Radiation Wound
Protective Blocking Filter™
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy
beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: February 15, 2006
Received: February 21, 2006

Dear Dr. Collins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Indications for Use

510(k) Number: K052383

Device Name: Innocure Intensity Modulating Radiation Therapy
Compensators including:

Innocure IMRT Filter™

Innocure IMRT Radiation Blocking Filter™

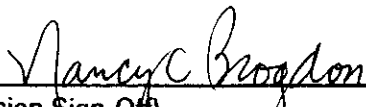
Innocure Radiation Wound Protective Blocking Filter™

Indications for Use: Innocure Intensity Modulating Radiation Therapy Compensators are indicated to be used for external beam radiation therapy to modulate the intensity and shape of a radiation beam to compensate for missing tissue, for tissue heterogeneities, or to protect underlying tissue by intensity modulation, i.e. Intensity Modulated Radiation Therapy (IMRT).

Prescription Use YES
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K05-2383